American Orthotic and Prosthetic Association

1650 King Street, Suite 500, Alexandria, Virginia 22314 • Phone (703) 836-7116 • Fax (703) 836-0838

FILE COPY

February 27, 1996

Food and Drug Administration
Center for Devices and Radiological Health
2094 Gaither Road HFZ-84
Rockville, M D 20850
Attn.: Joseph Sheehan, Esq.

Dear Mr. Sheehan:

In March 1992, the American Orthotic and Prosthetic Association (AOPA) submitted a petition under section 513 of the Medical Device Amendments of 1976 (Public Law 94-295) to the Federal Food Drug, and Cosmetic Act (21 U.S.C. 360 c), as further amended by the Safe Medical Devices Act of 1990 (Public Law 101-629), to request the Commissioner of Food and Drugs to revoke the classification of the "External assembled lower limb prosthesis," (21 CFR 890.3500). We remain convinced that this would be the best action to assure fair treatment of the O&P industry and request prompt action on our above petition.

As you know, however, the Center for Devices and Radiological Health is in the process of down-classifying and/or exempting many Class II and Class I devices from premarket notification--510(k) requirements (FR vol.61, no. 10, Jan. 16, 1996). Without in any way compromising any actions you may take on the above petition, we wish to request an interim action on this device. AOPA respectfully requests the Commissioner to down-classify the "External assembled lower limb prosthesis," (21 CFR 890.3500), from Class II to Class I and exempt it from 510(k) requirements as you have just done for ten other physical medicine devices [FR vol. 61, no. 10, pp. 1117 - 26, Jan. 16, 1996].

AOPA firmly believes this would be a reasonable intermediate step and would ameliorate some of the problems our industry has had with FDA Investigators confusing this device with the "External limb prosthetic component" (21 CFR 890.3420) which is already Class I and exempt from premarket notification requirements.

92P-0173

SUP1

As a further basis for this request, I would point out that for the Classification Code (ISW) assigned to this CFR designation (CFR 890.3500) in "Classification Names for Medical Devices...FDA 95-4246, only three MDR reports have been filed since 1981. Two of these were for malfunction and one was for a serious injury caused by a hydraulic knee control. This paucity of adverse reports bolsters our request for down-classification and exemption from 510(k)s.

Your prompt consideration of this request will be appreciated. I look forward to hearing from you soon.

Sincerely,

Kathleen A. Dodson
Executive Director

cc: Charles K. Unger, CAE